Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Treatment of seasonal allergic rhinitis: an evidence-based focused 2017 guideline update.

Bibliographic Source(s)

Dykewicz MS, Wallace DV, Baroody F, Bernstein J, Craig T, Finegold I, Huang F, Larenas-Linnemann D, Meltzer E, Steven G, Bernstein DI, Blessing-Moore J, Dinakar C, Greenhawt M, Horner CC, Khan DA, Lang D, Oppenheimer J, Portnoy JM, Randolph CR, Rank MA. Treatment of seasonal allergic rhinitis: an evidence-based focused 2017 guideline update. Ann Allergy Asthma Immunol. 2017 Dec;119(6):489-511. [92 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Wallace DV, Dykewicz MS, Bernstein DI, Blessing-Moore J, Cox L, Khan DA, Lang DM, Nicklas RA, Oppenheimer J, Portnoy JM, Randolph CC, Schuller D, Spector SL, Tilles SA, Joint Task Force on Practice, American Academy of Allergy, Asthma & Immunology, American College of Allergy, Asthma and Immunology, Joint Council of Allergy, Asthma and Immunology. The diagnosis and management of rhinitis: an updated practice parameter. J Allergy Clin Immunol. 2008 Aug;122(2 Suppl):S1-84. [998 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source

▮▮▮▮▯	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition
YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▮▮	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▯	Rating the Strength of Recommendations
▮▮▮▮▮	Specific and Unambiguous Articulation of Recommendations
▮▮▮▮▯	External Review
▮▮▮▮▯	Updating

Recommendations

Major Recommendations

Definitions for the quality of evidence (high, moderate, low, very low) are provided at the end of the "Major Recommendations" field.

Specific Care Question 1

For the initial treatment of seasonal allergic rhinitis (SAR) in patients 12 years or older, is there any clinical benefit of using a combination of an oral antihistamine and an intranasal corticosteroid (INCS) compared with monotherapy with an INCS?

Clinical Statement

For initial treatment of nasal symptoms of SAR in patients 12 years or older, clinicians should routinely prescribe monotherapy with an INCS rather than a combination of oral antihistamines and INCSs. (Strength of recommendation as determined by the Joint Task Force on Practice Parameters [JTFPP]:

Strong [by Delphi, 7 voted strong and 1 voted weak]. GRADE evidence of quality as determined by the JTFPP: Moderate [by Delphi, 7 voted moderate and 1 voted weak].)

Specific Care Question 2

In patients with moderate to severe SAR who are 15 years or older, how does montelukast compare with an INCS in terms of clinical benefit?

Clinical Statement

For initial treatment of moderate to severe SAR in patients 15 years and older, the clinician should recommend an INCS over a leukotriene receptor antagonist (LTRA). (Strength of recommendation as determined by the JTFPP: Strong [by Delphi, 8 of 8 voted for strong]. GRADE evidence of quality as determined by the JTFPP: High [by Delphi, 8 of 8 voted for high].)

Specific Care Question 3

For initial treatment of nasal symptoms of SAR in patients with SAR who are 12 years or older, is there any clinical benefit of using the combination of an intranasal antihistamine (INAH) and an INCS compared with monotherapy with an INCS? For initial treatment of nasal symptoms of SAR in patients with SAR who are 12 years or older, is there any clinical benefit of using the combination of an INAH and an INCS compared with monotherapy with an INAH?

Clinical Statement

For treatment of nasal symptoms of moderate to severe SAR in patients 12 years or older, the clinician may recommend the combination of an INCS and an INAH for initial treatment. (Strength of recommendation as determined by the JTFPP: Weak [by Delphi, 8 of 8 voted for weak]. GRADE evidence of quality as determined by the JTFPP: High [by Delphi, 8 of 8 voted for high quality].)

Refer to the "Clinical Statement Profiles" in the original guideline document for additional information.

Definitions

Quality of Evidence

High	The team is very confident that the true effect lies close to the estimate of the effect.
Moderate	The team is moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	The team confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very Low	The team has very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Seasonal allergic rhinitis

Guideline Category

Assessment of Therapeutic Effectiveness

Treatment

Clinical Specialty

Allergy and Immunology

Family Practice

Internal Medicine

Otolaryngology

Pediatrics

Intended Users

Physicians

Guideline Objective(s)

- To highlight several quality improvement opportunities for clinicians in the care of allergic rhinitis (AR) and reduce unnecessary cost and variations in care
- To provide guidance to health care professionals for treatment of adult and adolescent patients (≥12-15 years of age) with AR

Target Population

Adult and adolescent patients (≥12-15 years of age) with allergic rhinitis

Interventions and Practices Considered

1. Monotherapy with an intranasal corticosteroid (INCS)
2. Combination therapy with an oral antihistamine and an INCS
3. Oral leukotriene receptor antagonists (LTRAs)
4. Combination therapy with an intranasal antihistamine and an INCS

Major Outcomes Considered

- Total nasal symptom score (TNSS)
- Daytime nasal symptoms score
- Nighttime nasal symptoms score
- Morning peak expiratory flow
- Evening peak expiratory flow
- Symptom-free days
- Albuterol free days
- Quality of life
- Nasal, eye, and headache symptoms
- Adverse effects

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Literature Search: Design and Inclusion and Exclusion Criteria

The updated literature search (dates inclusive of July 18, 2012, to June 29, 2016) used by the Rhinitis Workgroup for the 3 questions considered in this focused systematic review was based on the same search criteria, databases, and inclusion criteria that had been used by the Agency for Healthcare Research and Quality's (AHRQ's) search review up to July 18, 2012, with the exception of including only articles that involved human subjects and limited to those published in the English language. For these 3 specific questions, the AHRQ search criteria included randomized clinical trials (RCTs) of seasonal allergic rhinitis (SAR), of at least 2 weeks' duration during active pollen season for all individuals 12 years and older. Systematic reviews and meta-analysis that assessed relevant treatment comparisons, reported an outcome of interest, and were of high quality were included in the search. Nonrandomized trials and comparative observational studies that were blinded and controlled for confounders were also included in the search and were considered for use in the final analysis. Individuals 12 years and older were required to have a minimum 2-year history of SAR of mild to severe degree of severity, consistent with Allergic Rhinitis and Its Impact on Asthma (ARIA) guideline definitions of severity, have a positive percutaneous allergy skin test result within the year before study, and be devoid of any of the predetermined exclusion criteria, as determined by the investigators. Outcomes had to include patient-reported symptom scores and/or validated quality-of-life instruments. Although ocular symptoms are important and often included in SAR studies, there was no requirement that the included trials report ocular symptoms as an outcome measure. A description of the search strategy and criteria used by the AHRQ to update the 2012 literature search for queries 1, 2, and 3 are detailed in Appendix A, Tables 1, 2, and 3 in the original guideline document.

Literature Search: Databases and Results

For both the AHRQ and Rhinitis Workgroup literature searches, the following databases were searched for RCTs, nonrandomized trials, and comparative observational studies through June 29, 2016: MEDLINE (PubMed and Ovid), EMBASE (Ovid), and Cochrane Central Register of Controlled Trials (CENTRAL). For the AHRQ search of systematic reviews from January 1, 2010, to July 18, 2012, the following additional databases were searched: Cochrane Database of Systematic Reviews, and the Database of Abstracts and Reviews of Effects and the Health Technology Assessment databases of the Centre for Reviews and Dissemination. Articles were limited to those published in the English language. Gray literature through July 18, 2012, was sought by the AHRQ by searching FDA Web site, conference abstracts of relevant professional organizations, and the clinical trial registries of the U.S. National Institutes of Health and the World Health Organization. The AHRQ screened titles and abstracts to select full-text articles that were eligible for review. Trained teamed reviewers completed the review in a duplicate manner. These full-text articles were then reviewed for inclusion in the systematic review process. The AHRQ search identified 4,513 records of which 169 were eliminated because they were being duplicate articles, leaving 4,344 articles for a title and abstract screen. Subsequently, 4,059 references were excluded for not meeting predefined criteria, and 285 were selected for full-text review. These were combined with the 4 articles identified through gray literature and hand search. After removing the references that failed to

meet the inclusion criteria, 59 unique trials were identified of which 13 reference articles were used to address the 3 questions in the current systematic review.

The updated Rhinitis Workgroup literature search initially cast a large net for all articles published in regard to rhinitis and treatment with the therapies under consideration. This yielded the following total number of articles: PubMed MEDLINE, 6,536 records; PubMed EMBASE, 140,379; Ovid MEDLINE, 1,316; and Cochrane Trials Registry, 220; for a total of 148,451 articles. After the search terms were combined, the number of possibly relevant references for question 1 was 56, for question 2 was 20, and for question 3 was 40. A summary of the literature search is found in in Appendix A, Tables 4, 5, and 6 in the original guideline document. The details of the literature search are available in Appendix C in the original guideline document. (MEDLINE and Cochrane database printed search with review notes.) Two workgroup members reviewed all abstracts and selected full-text articles. None of the articles met the inclusion criteria that had been established.

Although the extended literature search conducted in 2016 by the Joint Task Force on Practice Parameters' (JTFPP's) Rhinitis Workgroup did not uncover any new articles that met the inclusion criteria, based on additional selected reviews by workgroup members, including references identified in other recent rhinitis GRADE analyses, the Rhinitis Workgroup selected 3 additional articles, all pertaining to question 1, for review by the methods group. However, these studies were excluded from the final analysis because required data were incomplete because of data reporting issues (see Appendix A, Table 7 in the original guideline document for details).

Number of Source Documents

For the Agency for Healthcare Research and Quality (AHRQ) systematic review, after removing the references that failed to meet the inclusion criteria, 59 unique trials were identified of which 13 reference articles were used to address the 3 questions in the current systematic review. None of the articles found in the updated search met the inclusion criteria that had been established.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence

High	The team is very confident that the true effect lies close to the estimate of the effect.
Moderate	The team is moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	The team confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
Very Low	The team has very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Efficacy and Safety Outcome Assessment: Forest Plots

The workgroup chose all variants of nasal with ocular symptom scores, rescue medication score, and Rhinoconjunctivitis Quality of Life Questionnaire (RQLQ) as outcome variables of efficacy. Continuous variables, such as nasal symptom scores, were analyzed in forest plots, and, where possible, the results of several trials were grouped. They chose local and systemic symptoms generally linked to allergic rhinitis (AR) medication (e.g., somnolence for oral antihistamines and nasal bleeding for intranasal corticosteroids [INCSs]) as outcome variables of safety.

Effect Size and Standardized Mean Difference (SMD)

Often when combining data from a large number of studies, which have outcome variables that are not uniform among the trials (e.g., some score nasal symptoms scores of 0–12, others of 0–24), the SMD is used to determine effect size. The SMD (Hedges g) is the difference between the 2 means divided by the pooled standard deviation (SD), with a correction for small sample bias. In general, when evaluating SMD, Cohen criteria are used to interpret SMD results, in which 0.2 is considered a small effect, 0.5 a moderate, and 0.8 or higher a large effect. The methods group made a decision to combine the data for all studies that used uniformly reported outcomes, such as total nasal symptom score (TNSS). However, for studies for which outcome variables were not uniform, these studies were evaluated separately; thus, SMD was not used.

Quality Assessment of the Included Studies: Risk of Bias Using GRADE Analysis

An assessment of risk of bias factors (random sequence generation, allocation concealment, blinding adequacy, completeness of data, reporting, and other potential biases) that may contribute to risk of bias was initially conducted independently by 3 reviewers (2 Children's Mercy, Kansas City, evidence-based practice scholars and J.A.B.) based on the Review Manager software criteria. One nonclinician reviewer (J.A.B.) conducted a draft evaluation on the methodologic quality of the evidence based on the GRADE criteria independently. The workgroup and ultimately the Joint Task Force reviewed these draft assessments, applied their assessments of clinical importance for each patient-important outcome, and determined an overall quality of evidence across outcomes. For studies in which there had been incomplete reporting of information that might affect bias assessment, an attempt was made to contact authors to provide additional information. On the basis of additional information received from authors (see Appendix B in the original guideline document) and the workgroup and Joint Task Force on Practice Parameters' (JTFPP's) assessment of the risk of bias using each end point, a final bias assessment was determined by the JTFPP using the modified Delphi process. The level of methodologic quality for the identified literature is summarized after each clinical question.

Certainty of the Body of Evidence Using GRADE Analysis

For GRADE analysis of the certainty of the evidence, 3 areas were evaluated: inconsistency, indirectness, and imprecision.

Inconsistency: studies are reviewed in terms of populations, interventions, and outcomes for similarity, or consistency, among the compared studies.

Indirectness: analysis occurs around comparisons, populations, and outcomes among intervention studies. Indirectness in comparisons occurs when one drug is compared with placebo and another drug is compared with placebo, but the researchers do not compare the first drug and the second drug in a head-to-head comparison. Indirectness in populations means that the population in which the drug was studied doe not reflect the population in which the study drug would be used. Indirectness of outcome refers to a primary or secondary outcome that does not exactly measure the intended outcome (e.g., improved quality of life related to rhinitis measured with the generic quality-of-life tool SP27 instead of the specific RQLQ) and thus is not powered for the outcome of choice.

Imprecision: when too few study participants were enrolled or too few events occurred in the study,

imprecision is detected.

The GRADE quality analysis defines the certainty of the evidence. There are 4 levels of evidence (see the "Rating Scheme for the Strength of the Evidence" field).

The GRADE system for evaluating the quality of evidence (http://gdt.guidelinedevelopment.org/app) defines the elements that guideline writing groups need to consider when evaluating the quality of references that address a specific outcome (i.e., change in TNSS). These elements include the risk of bias, described above, as well as the article design (e.g., randomized controlled trials [RCT], inconsistency, indirectness, imprecision, and other considerations). Articles are not individually graded for these components but are reviewed overall by the guideline writing group and assigned an overall quality rating. Although some guideline writing groups have tried to develop a point system for grading of individual articles, this is not part of the formal GRADE system and was not used in this systematic review. The methods group used by the JTFPP designed a rating of individual references to assist them in their analysis, focusing on the lowest-quality grade assigned to any individual reference as the grade for all of the references used to answer any single question (see Appendix B in the original guideline document). However, the JTFPP chose to follow the GRADE handbook and reviewed all articles together to determine the overall quality of the articles for each outcome. Each JTFPP member individually determined the quality rating and using the Delphi method, the JTFPP decided the overall quality assessment for each outcome of interest. This difference in approach to the quality assessment is reflected in the discussion within the Clinical Statement Profile for each of the 3 questions. As the final step, the JTFPP rated each outcome across all studies (i.e., for a body of evidence) followed by determining an overall quality of evidence across outcomes, again using the Delphi method. The separate quality assessment tables for each of the 3 questions are included within this document.

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Methods

The Rhinitis Workgroup that developed this guideline was composed of volunteers from the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) with a specific interest in the topic and the guideline process. The workgroup first developed a list of clinical questions regarding the use of single or combination medications for the treatment of allergic rhinitis (AR), considering relative efficacy, possible additional efficacy by combining medications, costs, adverse effects, and other related outcomes. The top 3 questions that best addressed relevant and controversial issues were selected for Grading of Recommendations, Assessment, Development and Evaluation (GRADE) analysis and are detailed in the Guideline Update Objective section of the original guideline document. These 3 questions were also part of the Agency for Healthcare Research (AHRQ) 2013 systematic review. The entire Joint Task Force on Practice Parameters (JTFPP) of the AAAAI and ACAAI reviewed and approved these questions before starting the literature search.

GRADE: From Quality of Evidence (Bias, Certainty) to Recommendations

After the quality of evidence is evaluated, the GRADE analysis continues to take into account 3 other factors to finally recommend or suggest in favor or against a certain treatment or action: safety of the intervention, cost, and patient's preference. As such, the GRADE analysis is not only a system focused on grading the level of evidence but also a much more complete system aimed at formulating recommendations, as its acronym indicates.

Throughout the development of this practice parameter, the workgroup used the GRADE approach. In formulating the replies to the 3 key questions, they took into account the quality of evidence for

treatment efficacy, combining this with patients' safety, achieving adherence, and cost.

Individual subgroups drafted the recommendations and justifications based on the GRADE analysis. Subsequently, all recommendations were reviewed by the workgroup and JTFPP. Both groups were provided the opportunity to comment, propose changes, and approve or disapprove each statement. Consensus was sought and reached for each recommendation's direction and strength. Actual or potential conflicts of interest were disclosed semiannually, and transparency of discussion was maintained. External peer review was through appointed official reviewers and membership at large of the AAAAI and the ACAAI. All comments were discussed by the JTFPP, and revisions made when the workgroup and JTFPP believed this to be appropriate.

Reaching Workgroup Consensus on Statements and Conclusions

The workgroup used a modified Delphi process for the determination of the strength of the recommendation and the statement profile for each question. The Delphi method is a structured, interactive, decision-making process used by a panel of experts to arrive at a consensus when there are differing views and perspectives. For any statement or conclusion for which there was a difference of opinion, a modified Delphi method was used. Workgroup members provided anonymous answers via email to the JTFPP administrative director to the questions being considered. The administrative director provided via teleconference an anonymous summary of the experts' answers and reasons they provided for their responses. The workgroup members discussed all the answers and then were encouraged to modify their answers on the next round(s) of email voting and teleconferences until a consensus was reached.

Rating Scheme for the Strength of the Recommendations

Rating Scheme for the Strength of the Recommendations

Strong (with high-quality evidence)	Benefits clearly outweigh risks and burdens. Recommendations can apply to most patients in most circumstances. Further research is very unlikely to change our confidence in the estimate of the effect.
Strong (with moderate-quality evidence)	Benefits clearly outweigh risks and burdens. Recommendations can apply to most patients in most circumstances. Higher quality research may well have an important impact on our confidence in the estimate of effect and may change the estimate.
Strong (with low- or very low-quality evidence	Benefits clearly outweigh risks and burdens. Recommendations can apply to most patients in most circumstances. Higher quality research is likely to have an important impact on our confidence in the estimate of effect and may well change the estimate.
Weak (with high-quality evidence)	Benefits closely balanced with risks and burdens. The best action may differ depending upon circumstances or patient or societal values. Further research is very unlikely to change our confidence in the estimate of effect.
Weak (with moderate-quality evidence)	Benefits closely balanced with risks and burdens. The best action may differ depending upon circumstances or patient or societal values. Higher-quality research may well have an important impact on our confidence in the estimate of effect and may change the estimate.
Weak (with low- or very-low quality evidence)	Uncertainty in the estimates of benefits, risks, and burdens as these may be closely balanced. Other alternatives may be equally reasonable. Higher-quality research is likely to have an important impact on our confidence in the estimate of effect and may well change the estimate.

Cost Analysis

The Joint Task Force on Practice Parameters (JTFPP) understands that the cost of diagnostic tests and therapeutic agents is an important concern that may appropriately influence the workup and treatment chosen for a given patient. The JTFPP recognizes that the emphasis of our primary recommendations regarding a medication may vary, for example, depending on third-party payer issues and product patent expiration dates. However, because a given test or agent's cost is so widely variable, and there is a paucity of pharmacoeconomic data, the JTFPP generally does not consider cost when formulating practice parameter recommendations. In extraordinary circumstances, when the cost benefit of an intervention is prohibitive as supported by pharmacoeconomic data, commentary may be provided.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

Internal Review

A first draft of the guideline was sent to the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) appointment reviewers, who were asked to comment on the statements and the rationale within free text fields. All these comments and suggestions were discussed during a Joint Task Force on Practice Parameters (JTFPP) teleconference. The JTFPP liaison to the workgroup coordinated input from the workgroup when needed. For each comment or suggestion, the JTFPP evaluated whether the statement needed to be adapted, again taking into account the balance between desirable and undesirable consequences of the alternative management strategies, the quality of the evidence, and the variability in values and preferences.

External Review

The guideline was posted on the AAAAI, ACAAI, and JTFPP Web sites for all members and the public at large to review. For each comment or suggestion, the JTFPP evaluated whether the statement needed to be adapted, again taking into account the balance between desirable and undesirable consequences of the alternative management strategies, the quality of the evidence, and the variability in values and preferences.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Thirteen studies are reported as single trials. One meta-analysis reported study findings from 3 trials, one of which was also included as a single trial already included in this analysis and therefore was not repeated. Twelve of the studies were randomized, double-blind, placebo-controlled, parallel-group trials, and one study used a double-blind, placebo-controlled, crossover study design.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Potential cost saving, improving adherence, reduced adverse effects, greater convenience with intranasal corticosteroid (INCS) monotherapy compared with combination therapy with INCS and oral antihistamine.
- Promoting effective monotherapy with INCSs will decrease variation in care, with no decrement in the ability to bring symptoms under control, and improve quality of life, including sleep and work and school performance.
- Because some oral antihistamines, mainly first-generation antihistamines, may cause sedation or adverse effects, such as dryness of mouth and eyes, constipation, and inhibition of micturition, monotherapy with INCS would avoid these potential antihistamine-induced adverse effects.
- Compared to leukotriene receptor antagonists (LTRAs) use of the more effective therapy, INCSs, will increase clinical benefit, will decrease variations in care, and should result in a cost saving to society.
- One can achieve greater control of seasonal allergic rhinitis (SAR) with combination therapy than with monotherapy of INCS or intranasal antihistamines (INAH). The option of using a single intranasal spray device that contains both types of agents provides more convenient administration but with increased cost and, possibly, no greater benefit than the use of 2 separate nasal spray devices each of which contain one type of agent.

See the "Advice for the Clinician" section for each question in the original guideline document for benefits of specific interventions.

Potential Harms

- Although local adverse effects are typically minimal with the use of intranasal corticosteroids (INCSs), nasal irritation and bleeding and, rarely, nasal septal perforation may occur. After long-term use in susceptible populations, cataracts, increased intraocular pressure, and glaucoma have been reported, especially when combined with inhaled or oral corticosteroids. Although it is beyond the scope of this review, product labeling recommends that the growth of pediatric patients receiving INCSs should be routinely monitored. The package inserts for all INCSs also recommend monitoring for intraocular pressure, glaucoma, and cataracts.
- For montelukast, headache is the most common adverse effect and is reported more frequently than placebo in controlled trials. There are postmarketing reports with montelukast of rare neuropsychiatric events (e.g., aggression, depression, suicidal thinking, behavioral changes, dream abnormalities), which appear consistent with a drug-induced effect.
- The addition of an intranasal antihistamines (INAH) to an INCS increases the potential for harm based on the risk of an adverse effect. Adverse effects include sedation and/or unpleasant taste from INAHs beyond potential nosebleeds from INCSs. Using a single intranasal device that contains 2 medications increases the cost of therapy for most patients. Concurrent therapy with both agents in separate devices is also a greater cost than that of monotherapy with either agent.

See the "Advice for the Clinician" section for each question in the original guideline document for adverse events of specific interventions.

Qualifying Statements

Qualifying Statements

Even though a number of these treatments are approved for younger children, the application of recommendations to children with AR would be partially based on data extrapolation from adult studies and would therefore be less certain. Recommendations in this document may not be applicable to all populations with AR and should not replace individualization of patient care or clinical judgment. Although the inclusion criteria for analyzed studies was for mild to severe AR, the studies that met all the inclusion

criteria included, overwhelmingly, patients with moderate to severe symptoms of SAR. Therefore, these conclusions may not apply to patients with mild SAR. As medical treatment evolves, future data may mandate further revision of these recommendations. In the Discussion section of the original guideline document, the workgroup also outlines questions for which further research is required.

Disclaimer

The American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) have jointly accepted responsibility for establishing Treatment of Seasonal Allergic Rhinitis: An Evidence-Based Focused 2017 Guideline Update. This is a complete and comprehensive document at the current time. The medical environment is changing, and not all recommendations will be appropriate or applicable to all patients. Because this document incorporated the efforts of many participants, no single individual, including members serving on the Joint Task Force on Practice Parameters (JTFPP), are authorized to provide an official AAAAI or ACAAI interpretation of these practice parameters. Any request for information or interpretation of this practice parameter by the AAAAI or ACAAI should be directed to the executive offices of the AAAAI and the ACAAI. These parameters are not designed for use by the pharmaceutical industry in drug development or promotion. The JTFPP understands that the cost of diagnostic tests and therapeutic agents is an important concern that may appropriately influence the workup and treatment chosen for a given patient. The JTFPP recognizes that the emphasis of our primary recommendations regarding a medication may vary, for example, depending on third-party payer issues and product patent expiration dates. However, because a given test or agent's cost is so widely variable, and there is a paucity of pharmacoeconomic data, the JTFPP generally does not consider cost when formulating practice parameter recommendations. In extraordinary circumstances, when the cost benefit of an intervention is prohibitive as supported by pharmacoeconomic data, commentary may be provided. These parameters are not designed for use by pharmaceutical companies in drug promotion. The JTFPP is committed to ensuring that the Practice Parameters are based on the best scientific evidence that is free of commercial bias. To this end, the parameter development process includes multiple layers of rigorous review. These layers include the work group convened to draft the parameter, the task force reviewers, and peer review by members of each sponsoring society. Although the JTFPP has the final responsibility for the content of the documents submitted for publication, each reviewer's comments were discussed and reviewers received written responses to comments when appropriate. To preserve the greatest transparency regarding potential conflicts of interest, all members of the JTFPP and the practice parameters work groups will complete a standard potential conflict of interest disclosure form, which will be available for external review by the sponsoring organization and any other interested individual. In addition, before confirming the selection of a work group chairperson, the JTFPP will discuss and resolve all relevant potential conflicts of interest associated with this selection. Finally, all members of parameter work groups will be provided a written statement regarding the importance of ensuring that the parameter development process is free of commercial bias.

Qualifying Statements

This clinical practice guideline was designed to facilitate informed decision making on the management of adults with seasonal allergic rhinitis (SAR). It was not intended to define a standard of care and should not be construed as such. It should not be interpreted as a prescription for an exclusive course of management.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Dykewicz MS, Wallace DV, Baroody F, Bernstein J, Craig T, Finegold I, Huang F, Larenas-Linnemann D, Meltzer E, Steven G, Bernstein DI, Blessing-Moore J, Dinakar C, Greenhawt M, Horner CC, Khan DA, Lang D, Oppenheimer J, Portnoy JM, Randolph CR, Rank MA. Treatment of seasonal allergic rhinitis: an evidence-based focused 2017 guideline update. Ann Allergy Asthma Immunol. 2017 Dec;119(6):489-511. [92 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Dec

Guideline Developer(s)

American Academy of Allergy, Asthma and Immunology - Medical Specialty Society

American College of Allergy, Asthma and Immunology - Medical Specialty Society

Source(s) of Funding

This work was funded by the American Academy of Allergy, Asthma, Immunology and the American College of Allergy, Asthma, and Immunology.

Guideline Committee

Joint Task Force on Practice Parameters (JTFPP)

Rhinitis Workgroup

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Disclosures

All members of the Rhinitis Workgroup and the Joint Task Force on Practice Parameters (JTFPP) were required to complete a detailed declaration of interest statement, including all current and future conflicts of interest and past conflicts of interest restricted to 2 years before joining the workgroup and/or the JTFPP. It is believed that excluding all individuals with some degree of potential conflict of interest would prevent the assembly of a workgroup and the JTFPP. The authors therefore allowed members of the workgroup and the JTFPP to have past financial and/or intellectual conflicts of interest. No consequences were attached to the stated interests, but rather the authors insisted on transparency. All members of the workgroup and the JTFPP were allowed to participate in all discussions and had equal weight in

formulating the statements. All were allowed equal involvement in data extraction and writing the rationales. The declaration of interest forms are available from www.allergyparameters.org and are updated on a regular basis. A summary of interests disclosed on work group members' conflict of interest disclosure statements (not including information concerning family member interests) can be found in the article's online repository and at www.allergyparameters.org. Completed conflict of interest disclosure statements are available on request. The JTFPP recognizes that experts in a field are likely to have interests that could come into conflict with the development of a completely unbiased and objective practice parameter. To take advantage of that expertise, a process has been developed to prevent potential conflicts from influencing the final document in a negative way. At the workgroup level, all the sections are reviewed by all workgroup members to determine whether the content is appropriate and without apparent bias. If a section is deemed to have apparent bias, it will be appropriately revised without the section author's involvement to remove potential bias.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Wallace DV, Dykewicz MS, Bernstein DI, Blessing-Moore J, Cox L, Khan DA, Lang DM, Nicklas RA, Oppenheimer J, Portnoy JM, Randolph CC, Schuller D, Spector SL, Tilles SA, Joint Task Force on Practice, American Academy of Allergy, Asthma & Immunology, American College of Allergy, Asthma and Immunology, Joint Council of Allergy, Asthma and Immunology. The diagnosis and management of rhinitis: an updated practice parameter. J Allergy Clin Immunol. 2008 Aug;122(2 Suppl):S1-84. [998 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available to subscribers from the Annals of Allergy, Asthma, and Immunology Web site.

Availability of Companion Documents

The following are available:

Glacy J, Putnam K, Godfrey S, Falzon L, Mauger B, Samson D, Aronson N. Treatments for seasonal allergic rhinitis. Comparative Effectiveness Review No. 120. AHRQ Publication No. 13-EHC098-EF. Rockville (MD): Agency for Healthcare Research and Quality; 2013 Jul. 366 p. Available from the Agency for Healthcare Research and Quality (AHRQ) Web site.

Wallace DV, Dykewicz MS, Oppenheimer J, Portnoy JM, Lang DM. Pharmacologic treatment of seasonal allergic rhinitis: synopsis of guidance from the 2017 Joint Task Force on Practice Parameters. Ann Int Med. 2017 Sep;167(12):876-81. Available from the Annals of Internal Medicine Web site.

Patient Resources

None available

NGC Status

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